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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,653	01/29/2001	M. Pamela Griffin	10406/16	7814

34444 7590 03/19/2003

UNIVERSITY OF VIRGINIA PATENT FOUNDATION
1224 WEST MAIN STREET, SUITE 1-110
CHARLOTTESVILLE, VA 22903

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/770,653

Applicant(s)

GRIFFIN ET AL.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/16/03 (RCE and Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-69 and 71-80 is/are pending in the application.
- 4a) Of the above claim(s) 50,51,58,63-67,74 and 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-49,52-57,59-62,68,69,71-73,75 and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 & 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 1/16/03 has been entered.

Claim Rejections - 35 USC § 102

2. Claims 39, 40, 42, 44-49, 52-56, 62, 68-69, 71-73 and 75-76 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. (US4862361). Gordon et al. disclose use of heart rate power spectral analysis to monitor cardiovascular regulation as an indicator of physiological disturbance of the circulatory system homeostasis. Stable and unstable graphic depictions of the parameters are shown in figures 10 and 11 (c 17, ll 29-41). Stable and unstable data sets graphically charted in figures 16, 17 and 18 show the distribution of heart rate variability data for 29 ill children monitored in a study (c 23, ll 35-51).

As to claims 39, 40, 42, 44, 47, 49, 54, 56, 62 and 69, Gordon et al. teach a critically ill child may exhibit marked changes in heart rate, read to be heart rate variability, indicative of a major unrecognized pathology. When a child has myocarditis (an inflammation of the muscular walls of the heart incidental to systemic disease), low frequency heart rate fluctuations are seen (c 4, l 54 - c 5, l 7). The systemic disease as disclosed by Gordon et al. may be a severe systemic infection (c 26, ll 42-51); it is inherent that severe systemic infections significant for an infant or neonate include necrotizing enterocolitis, pneumonia, sepsis and meningitis.

As to claims 39, 46, 55, 68, 69, 71 and 72, the R-R intervals are measured, collecting 1024 points (a ten to the third order data set), and third moment and higher data set is created by a microprocessor using the mean heart rate to calculate a "tachometer waveform" and by using the respiratory peak within a peak and judging the value against a value of two standard deviations from the mean. (c 5, l 22 – c 6, l 7).

As to claims 45, 48, 52, 53, 73, 75 and 76, a slew rate, read as the skew rate, is calculated using normalized data, a mean variance and a maximum of 10% of the heart rate waveform readings (c 16, l 64 – c 17, l 28).

The Applicant's arguments filed 1/16/03 have been fully considered but they are not convincing. The rejection of record has been amended to include references to the specific claim elements, as the Applicant noted this correlation was missing from the rejection.

The Applicant argues that since Gordon et al. and the Applicants use an entirely different mathematical approach to detect illness in the infant, the instant invention is not disclosed by Gordon et al.. The Examiner disagrees.

In response to the Applicant's arguments that the references fail to show certain features of the Applicant's invention, it is noted that the features upon which the Applicant relies (i.e., calculating third and higher moments of the heart rate data as described in the instant invention, and not calculating the skewness of the RR interval histogram as described in the instant invention) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The method for calculating the third

moment and higher data set is also not claimed by the Applicant, hence it is a moot point that the Applicants do not calculate the third moment and higher data set using a tachometer waveform and the respiratory peak. The Examiner agrees there are differences in the approaches use by the Applicants and Gordon et al., but as currently claimed, Gordon et al. and the combination of Gordon et al. and Schroepel et al. are deemed to read on the rejections of record, hence the rejections stand.

Claim Rejections - 35 USC § 103

3. Claims 41, 43, 57 and 59-61 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 4862361) in view of Schroepel et al. (US 6035233). As discussed in paragraph 4 of this action, Gordon et al. discloses the claimed invention except for, upon identification of heart rate variability, providing a diagnostic work-up for the illness, including a blood culture or a pathological specimen, and antibiotics to treat the infection.

Schroepel et al. disclose an implantable device responsive to heart rate variability and teach that, when heart rate variability is identified, it is known to selectively provide increasingly aggressive therapy regimes, beginning with a diagnostic work-up that would inherently include a blood culture and if additional signs of infection were present, such as an elevated temperature, a pathological specimen to identify any potential infection in the lungs or the spinal fluid. Drug therapy is a noted step in the therapy regime; antibiotics are inherent as the drug treatment for an infection (c 9, ll 3-45). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart rate power spectral analysis as taught by Gordon et al., with the diagnostic work-up for the illness, including a blood culture or a

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pathological specimen, and antibiotics as taught by Schroepel et al. to enable diagnosis of the potential fatal illness so effective treat may be rapidly undertaken to optimize the patient chances for recovery.

Other Prior Art Cited

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4298011 to Mangurten et al. teaches the use of blood cultures to diagnosis infections.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

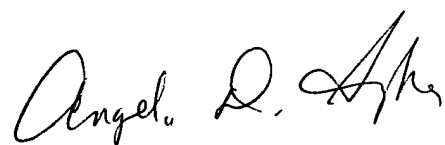
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
3/14/03



ANGELA D. SYKES
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